# STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BUREAU OF PROFESSIONAL LICENSING BOARD OF PHARMACY DISCIPLINARY SUBCOMMITTEE

In the Matter of

CARPENTER PHARMACY License Nos. 53-01-007734 and 53-15-015095,

File No. 53-18-149478

Respondent.

# ORDER OF SUMMARY SUSPENSION AND FOR SEIZURE OF CONTROLLED SUBSTANCES

The Department filed an *Administrative Complaint* against Respondent as provided by the Public Health Code, MCL 333.1101 *et seq.*, the rules promulgated under the Code, and the Administrative Procedures Act, MCL 24.201 *et seq.* 

After careful consideration and after consultation with the Chairperson of the Board of Pharmacy pursuant to MCL 333.7314(2), the Department finds that there is an imminent danger to the public health or safety that requires emergency action.

Therefore, IT IS ORDERED that Respondent's controlled substance license is SUMMARILY SUSPENDED, commencing the date this *Order* is served.

IT IS FURTHER ORDERED that, pursuant to Article 7 of the Code, MCL 333.7101 *et seq.*, all controlled substances owned or possessed by Respondent at the time the *Administrative Complaint* was filed before the Disciplinary Subcommittee shall be seized by the Department pending completion of proceedings.

Under Mich Admin Code, R 792.10702, Respondent may petition for the dissolution of this *Order* by filing a document clearly titled **Petition for Dissolution of Summary Suspension** with the Department of Licensing and Regulatory Affairs, Bureau of Professional Licensing, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

Dated: <u>///</u>, 2018

By: Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing

Order of Summary Suspension File Number: 53-18-149478

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## ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs by Cheryl Wykoff Pezon, Director, Bureau of Professional Licensing, complains against Respondent Carpenter Pharmacy as follows:

- The Michigan Board of Pharmacy is an administrative agency established by the Public Health Code, MCL 333.1101 et seq. The Board's Disciplinary Subcommittee is empowered to discipline licensees for Code violations.
- 2. The Board administers the controlled substance provisions in Article 7 of the Code, MCL 333.7101 .7545, and is empowered to discipline licensees for Article 7 violations under MCL 333.7311.
  - 3. MCL 333.7333(1) provides, in pertinent part:

"[G]ood faith" means the prescribing or dispensing of a controlled substance by a practitioner . . . to or for an individual . . . . Application of good faith to a pharmacist means the dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

(a) Lack of consistency in the doctor-patient relationship.

- (b) Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients.
- (c) Quantities beyond those normally prescribed for the same drug.
- (d) Unusual dosages.
- (e) Unusual geographic distances between patient, pharmacist, and prescriber.
  - 4. Mich Admin Code, R 338.490(2) provides:

A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

- (a) The prescription appears to be improperly written.
- (b) The prescription is susceptible to more than 1 interpretation.
- (c) The pharmacist has reason to believe that the prescription could cause harm to the patient.
- (d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.
- 5. Respondent holds a pharmacy license no. 53-01-007734 and a controlled substance license no. 53-15-015095. After consultation with the Board Chairperson, the Department found that there is an imminent danger to the public health or safety that warrants suspension of Respondent's controlled substance license. Therefore, pursuant to MCL 333.7314(2), the Department summarily suspended Respondent's State of Michigan controlled substance license, effective on the date the accompanying Order of Summary Suspension was served.
- 6. Respondent is a licensed pharmacy located in Hamtramck, Michigan. Upon information and belief, Respondent's part-owner and pharmacist-in-charge (PIC) is Hien Dien Ha, R.Ph.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup>The Department has also filed an Administrative Complaint against Ha for the conduct alleged here. *Hien Dien Ha, R.Ph.,* No. 53-18-149477.

7. Alprazolam is a benzodiazepine schedule 4 controlled substance.

Alprazolam is a commonly abused and diverted drug, particularly in its 1 mg and 2 mg

dosages.

8. Carisoprodol is a muscle relaxant and a schedule 4 controlled

substance. Carisoprodol has significant potential for abuse, dependence, overdose, and

withdrawal, particularly when used in conjunction with opioids and benzodiazepines.

9. Promethazine with codeine syrup is a schedule 5 controlled

substance prescribed for treating cough and related upper respiratory symptoms.

Promethazine with codeine syrup is rarely indicated for any other health condition and is

particularly ill-suited for long-term treatment of chronic pain. Promethazine with codeine

syrup is a highly sought-after drug of abuse, and is known by the street names "lean,"

"purple drank," and "sizzurp."

10. Gabapentin, a prescription medication, is used as an anticonvulsant

and a peripheral neuropathy agent. Gabapentin is known to be abused and diverted.

11. Hydrocodone, and combination products including hydrocodone are

commonly abused and diverted opioid schedule 2 controlled substances.

12. Oxycodone, and combination products including oxycodone, are

opioid schedule 2 controlled substances and are commonly abused and diverted.

13. Oxymorphone, a schedule 2 controlled substance, is an opioid used

to treat pain, and is a commonly abused and diverted drug. Oxymorphone 40 mg is the

most commonly abused and diverted strength of oxymorphone.

14. Zolpidem (e.g., Ambien), a schedule 4 controlled substance, is a non-benzodiazepine sedative used to treat sleep disorders, and is commonly abused and

diverted.

15. When used in combination, opioids, carisoprodol, and

benzodiazepines can produce a feeling of euphoria. These combinations are highly

desired for diversion and abuse and have the street name "Holy Trinity."

16. The Centers for Disease Control and Prevention (CDC) guidelines

for opioid prescribing direct providers to avoid prescribing opioid pain medication and

benzodiazepines concurrently whenever possible.

17. The CDC's guidelines for opioid prescribing direct providers to use

"extra precautions" when prescribing opioids with a daily morphine milligram equivalent

(MME) of 50 or more. Those guidelines also direct providers to "avoid or carefully justify"

increasing dosage to a daily MME of 90 or more.

18. The Department reviewed data from the Michigan Automated

Prescription System (MAPS), the State of Michigan's prescription monitoring program,

which gathers data regarding controlled substances dispensed in Michigan. Though the

data showed Respondent was not a high-volume dispenser of controlled substances

overall, the Department discovered that Respondent was among the highest-ranked

dispensers of the following commonly abused and diverted controlled substances among

all Michigan dispensers during 2015, 2016, and each quarter of 2017:

Drug	2015 Rank	2016 Rank	2017 Rank Q1	2017 Rank Q2	2017 Rank Q3	2017 Rank Q4
Alprazolam 1 mg	5	4	6	6	8	18
Carisoprodol 350 mg	28	6	2	1	1	3
Oxycodone 30 mg	4	5	17	22	15	15
Oxymorphone 40 mg	64	50	42	31	19	8
Promethazine with Codeine	4	3	3	1	1	2

19. During the following periods, Respondent dispensed prescriptions for the following commonly abused and diverted controlled substances in the following quantities:

	Drug	2015	2016	2017
(a)	Alprazolam 1 mg	2,201	1,988	1,453
		(17.27%)	(16.22%)	(13.58%)
(b) Hy	Hydrogodono onon 7 5 225 mg	1,760	1,634	1,274
	Hydrocodone-apap 7.5-325 mg	(13.81%)	(13.33%)	(11.91%)
(c)	Hydrocodone-apap 10-325 mg	1,507	1,722	1,459
		(11.83%)	(14.05%)	(13.64%)
(d) Promethazine wit	D	1,230	1,217	1,102
	Promethazine with Codelne	(9.65%)	(9.93%)	(10.30%)
(e) Oxycodone 30 mg	0	1,092	842	660
	Oxycodone 30 mg	(8.57%)	(6.87%)	(6.17%)
(f)	Carisoprodol 350 mg	466	620	590
		(3.66%)	(5.06%)	(5.52%)
(g)	Total, (a) - (f)	8,256	8,023	6,538
		(64.78%)	(65.44%)	(61.11%)
(h)	Total CS prescriptions	12,744	12,260	10,698

# Pharmacy Inspection and Operations

- 20. On April 4, 2018, the Department inspected Respondent's place of business and discovered the following violations of rules governing the practice of pharmacy:
  - a. Respondent was missing required reference materials.
  - b. Respondent's sink did not have hot water.
  - c. Expired medications were found on the shelves.
  - d. Medication was repackaged with inaccurate expiration dates.

e. Respondent's PIC did not have his license posted.

21. On April 6 and April 12, 2018, Department investigators interviewed

Respondent's PIC regarding the findings from the April 4, 2018 inspection and

Respondent's overall practice of pharmacy.

22. Respondent's PIC indicated he is the primary pharmacist at

Respondent, only occasionally having other pharmacists fill in when he is on vacation.

23. Respondent's PIC stated he checks MAPS when dispensing

oxycodone, oxymorphone, and hydrocodone-acetaminophen. Respondent's PIC

occasionally checks MAPS for other controlled substance prescriptions.

24. Respondent's PIC indicated that if he reviews MAPS and finds that

a patient is prescribed controlled substances by multiple prescribers, he will talk to the

patient.

25. Respondent's PIC stated he reviews MAPS to see if a patient is using

another pharmacy. He further stated he does not review how many prescribers a patient

is receiving prescriptions from, MME data, or how a patient is paying for prescriptions.

Respondent's PIC also indicated he does not review MAPS data for patterns, such as

dosing and duration of treatment. Respondent's PIC later contradicted his statement

about reviewing MMEs, stating that he does review MMEs when reviewing MAPS data.

26. Respondent's PIC acknowledged he was familiar with the CDC

guidelines for opioid prescribing, though he does not question prescribers about doses

prescribed.

Red Flags for Diversion

27. The Department's investigator informed Respondent's PIC that

Respondent dispensed approximately 472 pints of promethazine with codeine syrup in

2017, which is about nine pints per week. Respondent's PIC acknowledged that

Respondent had almost 18 pints in stock when the inspection was conducted.

Respondent's PIC was unaware promethazine with codeine syrup is indicated for short-

term, temporary relief. Respondent's PIC was also not aware promethazine with codeine

syrup was a diverted and abused controlled substance.

28. The Department's investigator later completed an audit worksheet

for controlled substances at Respondent which indicated a significant shortage of

promethazine with codeine syrup, approximately 39 pints.

29. Respondent's PIC stated that Respondent dispenses a significant

amount of gabapentin medication and did not realize that gabapentin was an abused and

diverted medication. Respondent's PIC was also unaware gabapentin was set to become

a controlled substance in Michigan. From January 1, 2018 through March 31, 2018,

Respondent dispensed 2,880 capsules of gabapentin 600 mg and 3,390 capsules of

gabapentin 800 mg. During the inspection of Respondent, the Department's investigator

found that Respondent had over 1,500 capsules of gabapentin 600 mg in stock and over

1,500 capsules of gabapentin 800 mg in stock.

30. Respondent's PIC stated he was aware many of the past prescribers

of prescriptions dispensed by Respondent have had Administrative Complaints and/or

were disciplined by boards in the state of Michigan. Respondent's PIC stated that when

he reviews MAPS, he does not look for a pattern that patients had a history of being treated by physicians who had been disciplined.

31. Respondent's PIC indicated that he signs the daily attest statement logs but does not review the log to see if there are any patterns of prescribers.

32. MAPS data revealed that many of Respondent's patients traveled to Respondent from outside Hamtramck. Respondent's PIC had no explanation for the traveling patients, other than they liked the services and were long-time customers. Respondent's PIC indicated he does not document conversations with patients regarding why they travel.

## Pattern Prescriptions and Traveling Patients

33. Respondent's PIC indicated that a caregiver would bring patients into Respondent in a group. All of these patients were being treated by Dr. "B," and the prescriptions being filled were all for either oxycodone 30 mg or oxymorphone 40 mg.

34. A review of MAPS data showed that Respondent dispensed a total of 63 prescriptions written by Dr. "B," for 12 different patients, from the issue date of July 7, 2017 to March 28, 2018. The prescriptions were all for oxycodone 30 mg (3%) and oxymorphone 40 mg (97%). The 63 prescriptions were all paid for in cash. Several of these patients traveled significant distances to fill their prescriptions at Respondent.

35. The Department reviewed Respondent's MAPS data and found patients were filling prescriptions from several other prescribers who appeared to be engaging in pattern prescribing. Among those prescribers were:

a. Dr. Asm Ahmed, who almost exclusively prescribes promethazine with codeine syrup and carisoprodol. The Department summarily suspended Dr. Ahmed's license to practice medicine and Dr. Ahmed has been indicted for

health care fraud and prescribing unnecessary controlled substances for cash.

b. Dr. Obioma Agomuoh, who mainly prescribes oxycodone 30 mg. Dr. Agomuoh was indicted in 2016 for health care fraud and unlawful distribution of schedule II to V controlled substances.

c. Dr "R," who repeatedly prescribes oxycodone and oxymorphone.

d. Prescriber "M," who repeatedly prescribes oxycodone 30 mg and oxymorphone 40 mg.

e. Dr. "K," who repeatedly prescribes oxycodone 30 mg.

Several of these prescribers' patients filling prescriptions at Respondent were listed in the State of Michigan's Offender Tracking Information System (OTIS) as having controlled substance-related convictions, among others.

Concerns Regarding Fraudulent Activity

36. A review of MAPS data indicated that patients filling controlled substance prescriptions at Respondent paid for 11.68% of these prescriptions in cash in 2015, 14.10% in 2016, 16.94% in 2017, and 14.70% from January 1, 2018 through March 28, 2018. These rates are higher than the state average of approximately 10% and there were significant increases in the percentage of controlled substance prescriptions paid for in cash since 2015.

37. Further review revealed that carisoprodol 350 mg, oxycodone 30 mg, oxymorphone 40 mg, and promethazine with codeine syrup made up 84% of the controlled substance prescriptions paid for in cash at Respondent in 2017 and 80% from January 1, 2018 through March 28, 2018. Respondent's PIC stated that cash payments are higher for these controlled substances because insurance stopped paying for oxymorphone and promethazine with codeine syrup. However, based on a review of

MAPS data for Respondent, insurance does pay for oxymorphone and promethazine with codeine syrup. Paying for prescriptions in cash can be indicative of receiving medications for illegitimate purposes.

38. Respondent's PIC provided the cash price for eight ounces (240 milliliters) of promethazine with codeine syrup, sixty tablets of oxymorphone 40 mg, and ninety tablets of oxycodone 30 mg. Using this information and Respondent's controlled substance invoices, the Department calculated Respondent's profit margins for these controlled substances when paid for in cash:

Drug	Cost	Retail	Profit	Mark Up
Promethazine with Codeine Syrup (8 ounces)	\$3.52	\$60.00	\$56.48	1,605%
Oxymorphone 40 mg (60 tablets)	\$536.40	\$1,080.00	\$543.60	101%
Oxycodone 30 mg (90 tablets)	\$26.41	\$630.00	\$603.59	2,285%

- 39. Applying these profit margins to MAPS data indicating the units of each controlled substance dispensed at Respondent and paid for in cash between January 1, 2017 and March 28, 2018, Respondent realized gross profits during the period of \$108,735.55 for dispensing oxycodone 30 mg tablets, \$135,428.88 for dispensing oxymorphone 40 mg tablets, and \$46,727.76 for dispensing promethazine with codeine syrup, for total gross profits of approximately \$290,000.00 for these three controlled substances.
- 40. During the April 4, 2018 inspection, the Department's investigator found approximately 38 labels for various inhalers in a drawer and the actual product was not attached. The Department's investigator requested copies of several of these labels,

however the copies were never provided to the investigator.<sup>2</sup> Collections of pre-printed labels not filled with the actual inhaler product is a red flag for fraudulent insurance billings.

### Specific Patient Examples

- 41. The Department's investigator questioned Respondent's PIC regarding MAPS data for 11 patients to whom Respondent dispensed prescriptions during the review period of March 30, 2013 through March 30, 2018. All of those patients repeatedly filled prescriptions for commonly abused and diverted controlled substances at Respondent during that period:
  - a. Patient LB<sup>3</sup> filled numerous controlled substance prescriptions at Respondent, including prescriptions for oxycodone, oxymorphone, promethazine with codeine, alprazolam, and carisoprodol. In several instances, two or more prescriptions were filled at Respondent on the same day. Patient LB filled multiple opioid prescriptions carrying high MMEs, commonly 135.00 or 240.00, from several different prescribers.
    - When confronted with the distance patient LB was traveling to Respondent to fill prescriptions, Respondent's PIC did not have an answer. Patient LB received several high MME prescriptions from Dr. "B;" Respondent's PIC indicated he never discussed the high MMEs with Dr. "B."
  - b. Patient DB filled several prescriptions for oxymorphone 40 and oxycodone 30 mg written by Dr. "B." carrying high MMEs. Respondent's PIC stated he did not know why patient DB was paying cash at Respondent when he was using insurance at another pharmacy. Patient DB received several high MME prescriptions from Dr. "B;" Respondent's PIC indicated he did not know why patient DB was receiving these high-MME prescriptions.
  - c. Patient GC filled numerous prescriptions for hydrocodone-acetaminophen and promethazine with codeine at Respondent throughout the review period, from several prescribers. Several times, these prescriptions were filled on the same day. Respondent's PIC stated he was unaware why patient GC was receiving treatment from so many prescribers. Respondent's PIC could not explain why patient GC needed large quantities of promethazine with codeine for such a long time.

<sup>&</sup>lt;sup>2</sup> The Department acknowledges Respondent's copier was not working the day of the inspection. When the investigator called the next day to obtain copies of the labels, the investigator was informed the labels and copies had been shredded.

<sup>&</sup>lt;sup>3</sup> Patients are identified by their initials to protect their identities.

- d. Patient AD repeatedly filled prescriptions for oxycodone 30 mg from several different providers at Respondent which carried MMEs of 90.00 to 135.00. When confronted with the distance patient AD was traveling to Respondent to fill prescriptions, Respondent's PIC did not have an answer. Respondent's PIC was aware patient AD had seen multiple prescribers in the past two years.
- e. <u>Patient CG</u> repeatedly filled promethazine with codeine prescriptions at Respondent throughout the review period. Patient CG consistently paid cash for these prescriptions. In between filling promethazine with codeine prescriptions at Respondent, patient CG was filling prescriptions for oxycodone 30 mg and/or oxymorphone 40 mg, mostly at one other pharmacy.

When confronted with patient CG's traveling, Respondent's PIC was not sure why patient CG was traveling from home in Macomb to a prescriber in Bloomfield to Respondent in Hamtramck. Respondent's PIC could not explain why patient CG was paying cash at Respondent and using insurance at another pharmacy, or why patient CG was using multiple prescribers and multiple pharmacies. Last, Respondent's PIC could not explain why patient CG was receiving a pint of promethazine with codeine for such a long period of time.

- f. Patient CH filled prescriptions for alprazolam, oxymorphone, oxycodone, and hydrocodone-acetaminophen over the review period, often filling combinations of these medications on the same day. Respondent's PIC could not explain why patient CH was receiving prescriptions from multiple prescribers. Respondent's PIC did not know the diagnosis for the long-term use and large quantity of promethazine with codeine.
- g. Patient WH filled prescriptions for carisoprodol, oxycodone, hydrocodone-acetaminophen at Respondent throughout the review period, repeatedly filling combinations on the same day. When filled on the same day, the oxycodone and hydrocodone-acetaminophen prescriptions carried a total daily MME of 220.00. Patient WH also filled several prescriptions for promethazine with codeine at Respondent. Respondent's PIC could not explain the multiple prescribers or the high MMEs for patient WH.
- h. <u>Patient FJ</u> filled multiple prescriptions for oxycodone, oxycodone-acetaminophen, hydrocodone-acetaminophen, and diazepam at Respondent over the review period. Several of patient FJ's opioid prescriptions carried high daily MMEs. When asked about distances patient FJ was traveling, Respondent's PIC could not explain why patient WH was traveling from home in Southfield to the prescriber in Troy to Respondent in

- Hamtramck. Respondent's PIC did not know why patient FJ was receiving prescriptions with such high MMEs.
- Patient KL filled multiple prescriptions for oxymorphone carrying daily MMEs of 240.00 and prescriptions for oxycodone carrying daily MMEs of 135.00 at Respondent from several different prescribers. Respondent's PIC did not know why patient KL was receiving prescriptions with such high MMEs.
- j. Patient JM filled a pattern of prescriptions over the review period, alternating filling oxycodone and promethazine with codeine at Respondent and filling hydrocodone-acetaminophen and/or alprazolam at another pharmacy. Recently, patient JM began filling alprazolam, promethazine with codeine, and oxycodone prescriptions on the same day at Respondent. Many of patient JM's oxycodone prescriptions carried daily MMEs of 180.00. Respondent's PIC did not know why patient JM needed such large amounts of promethazine with codeine for a long period of time or why patient JM needed such high MME dosing.
- k. <u>Patient AP</u> filled multiple prescriptions for promethazine with codeine, oxycodone, and zolpidem tartrate over the review period. In addition, patient AP filled several other opioid prescriptions at Respondent over the review period. When asked, Respondent's PIC did not know why patient AP was using multiple prescribers or why he was traveling distances to come to Respondent. Respondent's PIC also did not know why patient AP regularly needed promethazine with codeine for a long period of time and in such large quantities.

#### COUNT I

Respondent failed to maintain effective controls against diversion of controlled substances to other than legitimate and professionally recognized therapeutic, scientific, or industrial uses, in violation of MCL 333.7311(1)(e).

COUNT II

Respondent dispensed controlled substances for other than legitimate or

professionally recognized therapeutic, scientific, or industrial purposes, or outside the

Respondent's scope of practice, in violation of MCL 333.7311(1)(g).

**COUNT III** 

Respondent dispensed controlled substances without good faith, contrary

to MCL 333.7333(1) and in violation of MCL 333.7311(1)(h).

**COUNT IV** 

Respondent failed to keep records and maintain inventories in conformance

with the record-keeping and inventory requirements of federal law, contrary to MCL

333.7321 and in violation of MCL 333.7311(1)(h).

COUNT V

Respondent's conduct, as described above, evidences a failure to maintain

not less than two current or revised pharmacy reference texts, contrary to Mich Admin

Code, R 338.481(2), in violation of MCL 333.17768(1).

**COUNT VI** 

Respondent's conduct, as described above, evidences a failure to meet

minimum housing requirements for the pharmacy, contrary to Mich Admin Code, R

338.482, in violation of MCL 333.17768(1).

RESPONDENT IS NOTIFIED that, consistent with Mich Admin Code, R 338.1615(3), Respondent has 30 days from the date of receipt of this complaint to answer this complaint in writing and to show compliance with all lawful requirements for retention of the license. Respondent shall submit the response to the Bureau of Professional Licensing, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

MICHIGAN DEPARTMENT OF

LICENSING AND REGULATORY AFFAIRS

Dated: 6/8, 2018

By: Cheryl Wykoff Pezon, Director

Bureau of Professional Licensing

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